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UTILITY  
PATENT APPLICATION  
TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

|                        |  |
|------------------------|--|
| Attorney Docket No.    | PDT 120/121 DIV CON  |
| First Inventor         | Solomon S. Steiner   |
| Title                  | Purification and Stabilization of Peptide and Protein<br>Pharmaceutical Agents |
| Express Mail Label No. | EL 717 747 269 US  |

## APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

## ADDRESS TO:

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria VA 22313-1450

1. ☒ Fee Transmittal Form (e.g., PTO/SB/17)  
(Submit an original and a duplicate for fee processing)
2. ☒ Applicant claims small entity status.  
See 37 CFR 1.27.
3. ☒ Specification [Total Pages 29]  
(preferred arrangement set forth below)
  - Descriptive title of the invention
  - Cross Reference to Related Applications
  - Statement Regarding Fed sponsored R & D
  - Reference to sequence listing, a table, or a computer program listing appendix
  - Background of the Invention
  - Brief Summary of the Invention
  - Brief Description of the Drawings (if filed)
  - Detailed Description
  - Claim(s)
  - Abstract of the Disclosure
4. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets 2]
5. Oath or Declaration [Total Sheets 3]
  - a. ☐ Newly executed (original or copy)
  - b. ☒ Copy from a prior application (37 CFR 1.63(d))  
(for continuation/divisional with Box 18 completed)
  - i. ☐ DELETION OF INVENTOR(S)  
Signed statement attached deleting inventor(s)  
name in the prior application, see 37 CFR  
1.63(d)(2) and 1.33(b).
6. ☒ Application Data Sheet. See 37 CFR 1.76

7. ☐ CD-ROM or CD-R in duplicate, large table or  
Computer Program (Appendix)
8. Nucleotide and/or Amino Acid Sequence Submission  
(if applicable, all necessary)
  - a. ☐ Computer Readable Form (CRF)
  - b. Specification Sequence Listing on:
    - i. ☐ CD-ROM or CD-R (2 copies); or
    - ii. ☐ Paper
  - c. ☐ Statements verifying identity of above copies

## ACCOMPANYING APPLICATION PARTS

9. ☒ Assignment Papers (cover sheet & document(s))
10. ☒ 37 CFR 3.73(b) Statement ☒ Power of  
(when there is an assignee) Attorney
11. ☐ English Translation Document (if applicable)
12. ☒ Information Disclosure ☐ Copies of IDS  
Statement (IDS)/PTO-1449 Citations
13. ☒ Preliminary Amendment
14. ☒ Return Receipt Postcard (MPEP 503)  
(Should be specifically itemized)
15. ☐ Certified Copy of Priority Document(s)  
(if foreign priority is claimed)
16. ☐ Nonpublication Request under 35 U.S.C. 122  
(b)(2)(B)(i). Applicant must attach form PTO/SB/35  
or its equivalent.
17. ☒ Other: Items 9 and 10 are copies from  
Serial No. 10/224,761

18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:

☒ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: 10/224,761

Prior application information:

Examiner L. DiNola BaronArt Unit: 1615

For CONTINUATION OF DIVISIONAL APPS only; The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

## 19. CORRESPONDENCE ADDRESS

☒ Customer Number: 23579 OR ☐ Correspondence address below

|         |                                       |           |                |          |                |
|---------|---------------------------------------|-----------|----------------|----------|----------------|
| Name    | Patrea L. Pabst, Holland & Knight LLP |           |                |          |                |
| Address | 2000 One Atlantic Center              |           |                |          |                |
|         | 1201 West Peachtree Street            |           |                |          |                |
| City    | Atlanta                               | State     | GA             | Zip Code | 30309-3400     |
| Country | United States of America              | Telephone | (404) 817-8473 | Fax      | (404) 817-8588 |

|                   |                       |                                   |                   |
|-------------------|-----------------------|-----------------------------------|-------------------|
| Name (Print/Type) | Patrea L. Pabst, Esq. | Registration No. (Attorney/Agent) | 31,284            |
| Signature         |                       | Date                              | November 21, 2003 |

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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17548 U.S. PTO  
10/719734

112103

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**FEE TRANSMITTAL**  
**for FY 2004**

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$ ) 385.00**Complete if Known**

|                      |                            |
|----------------------|----------------------------|
| Application Number   | Continuation of 10/224,761 |
| Filing Date          | November 21, 2003          |
| First Named Inventor | Solomon S. Steiner         |
| Examiner Name        |                            |
| Art Unit             |                            |
| Attorney Docket No.  | PDT 120/121 DIV CON        |

**METHOD OF PAYMENT** (check all that apply)☒ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☒ Deposit Account:Deposit  
Account  
Number  
Deposit  
Account  
Name

50-1868

Holland &amp; Knight LLP

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☒ Credit any overpayments☒ Charge any additional fee(s) or any underpayment of fee(s)☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.**FEE CALCULATION****1. BASIC FILING FEE**

| Large Entity        |          | Small Entity |          | Fee Description        | Fee Paid            |
|---------------------|----------|--------------|----------|------------------------|---------------------|
| Fee Code            | Fee (\$) | Fee Code     | Fee (\$) |                        |                     |
| 1001                | 770      | 2001         | 385      | Utility filing fee     | 385.00              |
| 1002                | 340      | 2002         | 170      | Design filing fee      |                     |
| 1003                | 530      | 2003         | 265      | Plant filing fee       |                     |
| 1004                | 770      | 2004         | 385      | Reissue filing fee     |                     |
| 1005                | 160      | 2005         | 80       | Provisional filing fee |                     |
| <b>SUBTOTAL (1)</b> |          |              |          |                        | <b>(\$ ) 385.00</b> |

**2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE**

|                    |    | Extra Claims |   | Fee from below |       | Fee Paid |      |
|--------------------|----|--------------|---|----------------|-------|----------|------|
| Total Claims       | 10 | -20** =      | 0 | X              | 9.00  | =        | 0.00 |
| Independent Claims | 1  | -3** =       | 0 | X              | 43.00 | =        | 0.00 |
| Multiple Dependent |    |              | 0 |                |       |          | 0.00 |

| Large Entity                   |          | Small Entity |          | Fee Description  |
|--------------------------------|----------|--------------|----------|--|
| Fee Code                       | Fee (\$) | Fee Code     | Fee (\$) |  |
| 1202                           | 18       | 2202         | 9        | Claims in excess of 20                                     |
| 1201                           | 86       | 2201         | 43       | Independent claims in excess of 3                          |
| 1203                           | 290      | 2203         | 145      | Multiple dependent claim, if not paid                      |
| 1204                           | 86       | 2204         | 43       | ** Reissue independent claims over original patent         |
| 1205                           | 18       | 2205         | 9        | ** Reissue claims in excess of 20 and over original patent |
| <b>SUBTOTAL (2)</b> (\$ ) 0.00 |          |              |          |  |

\*\*or number previously paid, if greater; For Reissues, see above

**FEE CALCULATION** (continued)**3. ADDITIONAL FEES**

Large Entity | Small Entity

| Fee Code | Fee (\$) | Fee Code | Fee (\$) | Fee Description  | Fee Paid |
|----------|----------|----------|----------|--|----------|
| 1051     | 130      | 2051     | 65       | Surcharge - late filing fee or oath  |          |
| 1052     | 50       | 2052     | 25       | Surcharge - late provisional filing fee or cover sheet                     |          |
| 1053     | 130      | 1053     | 130      | Non-English specification  |          |
| 1812     | 2,520    | 1812     | 2,520    | For filing a request for <i>ex parte</i> reexamination                     |          |
| 1804     | 920*     | 1804     | 920*     | Requesting publication of SIR prior to Examiner action                     |          |
| 1805     | 1,840*   | 1805     | 1,840*   | Requesting publication of SIR after Examiner action                        |          |
| 1251     | 110      | 2251     | 55       | Extension for reply within first month                                     |          |
| 1252     | 420      | 2252     | 210      | Extension for reply within second month                                    |          |
| 1253     | 950      | 2253     | 475      | Extension for reply within third month                                     |          |
| 1254     | 1,480    | 2254     | 740      | Extension for reply within fourth month                                    |          |
| 1255     | 2,010    | 2255     | 1,005    | Extension for reply within fifth month                                     |          |
| 1401     | 330      | 2401     | 165      | Notice of Appeal   |          |
| 1402     | 330      | 2402     | 165      | Filing a brief in support of an appeal                                     |          |
| 1403     | 290      | 2403     | 145      | Request for oral hearing   |          |
| 1451     | 1,510    | 1451     | 1,510    | Petition to institute a public use proceeding                              |          |
| 1452     | 110      | 2452     | 55       | Petition to revive - unavoidable   |          |
| 1453     | 1,330    | 2453     | 665      | Petition to revive - unintentional   |          |
| 1501     | 1,330    | 2501     | 665      | Utility issue fee (or reissue)   |          |
| 1502     | 480      | 2502     | 240      | Design issue fee   |          |
| 1503     | 640      | 2503     | 320      | Plant issue fee  |          |
| 1460     | 130      | 1460     | 130      | Petitions to the Commissioner  |          |
| 1807     | 50       | 1807     | 50       | Processing fee under 37 CFR 1.17(q)  |          |
| 1806     | 180      | 1806     | 180      | Submission of Information Disclosure Stmt                                  |          |
| 8021     | 40       | 8021     | 40       | Recording each patent assignment per property (times number of properties) |          |
| 1809     | 770      | 2809     | 385      | Filing a submission after final rejection (37 CFR 1.129(a))                |          |
| 1810     | 770      | 2810     | 385      | For each additional invention to be examined (37 CFR 1.129(b))             |          |
| 1801     | 770      | 2801     | 385      | Request for Continued Examination (RCE)                                    |          |
| 1802     | 900      | 1802     | 900      | Request for expedited examination of a design application                  |          |

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

**SUBTOTAL (3)** (\$ ) 0.00**SUBMITTED BY**

Name (Print/Type) Patrea L. Pabst, Esq.

Registration No.  
(Attorney/Agent)

31,284

(Complete (if applicable))

Telephone (404) 817-8473

Signature

Date

November 21, 2003

**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PDT 120/121 DIV CON - 078374/00034

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Solomon S. Steiner, Rodney J. Woods, and Joseph W. Sulner

Serial No.: Continuation of 10/224,761

Express Mail Label  
No. EL 717 747 269 US

Filed: November 21, 2003

Date of Deposit: November 21, 2003

For: *PURIFICATION AND STABILIZATION OF PEPTIDE AND  
PROTEIN PHARMACEUTICAL AGENTS*

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**REQUEST FOR FILING A CONTINUATION APPLICATION  
UNDER 37 C.F.R. § 1.53(b)**

Sir:

Pursuant to 35 U.S.C. § 21(a), as amended by Public Law 97-247, and 37 C.F.R. §§ 1.10 and 1.53(b), Applicants enclose for filing the attached new patent application entitled "*Purification and Stabilization of Peptide and Protein Pharmaceutical Agents*". This application is a continuation of pending prior application Serial No. 10/224,761 filed August 20, 2002, entitled "*Purification and Stabilization of Peptide and Protein Pharmaceutical Agents*", by Solomon S. Steiner, Rodney J. Woods, and Joseph W. Sulner, which is a divisional of U.S. Serial No. 09/606,468 filed June 29, 2000 (now U.S. Patent No. 6,444,226), which claims priority to U.S. Serial No. 60/141,433 filed June 29, 1999. The application includes 1 page of abstract, 25 pages of specification, 3 pages of claims, 2 sheets of formal drawings, and a copy of the executed Declaration for Patent Application from prior application Serial No. 10/224,761.

Continuation of U.S.S.N. 10/224,761  
Filed: November 21, 2003  
**REQUEST FOR FILING A CONTINUATION**  
**APPLICATION UNDER 37 C.F.R. § 1.53(b)**  
Express Mail Label No.: EL 717 747 269 US  
Date of Deposit: November 21, 2003

Pursuant to 37 C.F.R. § 1.63(d), the copy of the executed Declaration for Patent Application included in the new application is a copy of the executed Declaration filed in parent application Serial No. 10/224,761, to which the new application claims benefit.

The inventorship for the claims in the new application is the same as in parent application Serial No. 10/224,761.

Enclosed are a Preliminary Amendment and an Information Disclosure Statement. Please amend the application in accordance with the Preliminary Amendment.

Enclosed from prior application Serial No. 10/224,761 are copies of the (a) Power of Attorney by Assignee of Entire Interest and Revocation of Prior Powers; (b) Statement Under 37 CFR §3.73(b); and (c) Notice of Recordation of Assignment Document.

Also enclosed are an (a) Application Data Sheet; (b) Utility Patent Application Transmittal; and (c) Fee Transmittal (in duplicate).

This application is entitled to claim small entity status pursuant to 37 C.F.R. § 1.27.

Enclosed is a check in the amount of \$385.00 to cover the filing fee for a small entity. It is believed that this is the proper filing fee since the application includes 1 independent claim and a total of 10 claims upon entry of the enclosed Preliminary Amendment.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-1868. To facilitate this process, Applicants enclose a duplicate of this transmittal.

The power of attorney in the prior application is to Patrea L. Pabst.


Continuation of U.S.S.N. 10/224,761  
Filed: November 21, 2003  
**REQUEST FOR FILING A CONTINUATION**  
**APPLICATION UNDER 37 C.F.R. § 1.53(b)**  
Express Mail Label No.: EL 717 747 269 US  
Date of Deposit: November 21, 2003

All correspondence concerning this application should be mailed to:

Customer No. 23579  
Patrea L. Pabst, Esq.  
HOLLAND & KNIGHT LLP  
2000 One Atlantic Center  
1201 West Peachtree Street, N.E.  
Atlanta, GA 30309-3400

This application is being filed on November 21, 2003, by mailing the application to  
Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA  
22313-1450 via the United States Postal Service "Express Mail Post Office to Addressee"  
Service under 37 C.F.R. § 1.10. The Express Mail Label number appears in the heading of this  
paper which is attached to the application papers pursuant to 37 C.F.R. § 1.10(b).

Respectfully submitted,

  
\_\_\_\_\_  
Patrea L. Pabst  
Reg. No. 31,284

Date: November 21, 2003

HOLLAND & KNIGHT LLP  
2000 One Atlantic Center  
1201 West Peachtree Street, N.E.  
Atlanta, Georgia 30309-3400  
(404) 817-8473 (Telephone)  
(404) 817-8588 (Fax)

Continuation of U.S.S.N. 10/224,761  
Filed: November 21, 2003  
**REQUEST FOR FILING A CONTINUATION**  
**APPLICATION UNDER 37 C.F.R. § 1.53(b)**  
Express Mail Label No.: EL 717 747 269 US  
Date of Deposit: November 21, 2003

**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10**

I hereby certify that this paper and any documents referred to as attached or enclosed are being deposited with the United States Postal Service on this date, November 21, 2003, in an envelope as "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10, Express Mail Label No. EL 717 747 269 US, addressed to Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

  
\_\_\_\_\_  
Jean Hicks

Date: November 21, 2003

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